



DEVICE DETAILS

NAME OF DEVICE	COPE MANDRIL WIRE GUIDE NITINOL
ESTABLISHMENT NAME	COOK ASIA (MALAYSIA) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GD7124621-74290
BRAND NAME	COOK
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Cope Mandril Wire Guide Nitinol consists of a core mandril tapered on the distal end and a spring coil anchored over the distal portion of the mandril. The core mandril of the subject device is constructed of nitinol material and the spring coil is constructed of platinum material. The spring coil covers the distal, tapered portion of the core mandril and is anchored to the tapered tip of the core mandril with a weld. The proximal end of the spring coil is anchored using a solder connection proximal to the tapered portion of the core mandril. The Cope Mandril Wire Guide is available with an outside diameter ranging from 0.015 inches to 0.018 inches and lengths ranging from 25 centimeters (cm) to 180 cm. The flexible tip portion of the subject device is angled. The Mandril Wire Guide is a packaged, sterile device intended for single use.
DEVICE INTENDED PURPOSE	The Cook Cope Mandril Wire Guide Nitinol is intended to facilitate the placement of devices during diagnostic and interventional procedures.
VALIDITY DATE OF REGISTRATION	23/09/2021 - 22/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Cope Mandril Wire Guide Nitinol	PMG-18SP-125-COPE-NT
2	Cope Mandril Wire Guide Nitinol	PMG-18SP-60-COPE-NT